

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL
INDUSTRY AVERAGE
WHOLESALE PRICE LITIGATION

)
) MDL No.1456
)
) Master File No. 01-CV-12257-PBS
) Subcategory No. 06-CV-11337-PBS
)

THIS DOCUMENT RELATES TO:
U.S. of America ex rel. Ven-A-Care
of the Florida Keys, Inc., et al. v.
Boehringer Ingelheim Corporation, et al.,
Civil Action No. 07-10248-PBS

) Judge Patti B. Saris
)
) Magistrate Judge Marianne B. Bowler
)
)
)

**THE ROXANE DEFENDANTS' OPPOSITION TO
PLAINTIFF'S MOTION TO CONSOLIDATE CASES FOR TRIAL**

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Dated: November 2, 2009

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INTRODUCTION

Defendants Boehringer Ingelheim Roxane, Inc., Roxane Laboratories, Inc., Boehringer Ingelheim Corp. (“BIC”), and Boehringer Ingelheim Pharmaceuticals, Inc. (“BIPI”), (collectively, the “Roxane Defendants”), oppose the motion of the Department of Justice (“DOJ”) to consolidate for trial the separate case against the Roxane Defendants, *United States ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Boehringer Ingelheim Corp., et al.*, Civil Action No. 07-10248-PBS, with the case against Dey, Inc., Dey L.P., Inc. and Dey L.P. (“Dey Defendants”), *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey, Inc., et al.*, No. 05-CV-11084-PBS.¹ (*See* Dkt. No. 6584)

Consolidation of the Roxane and Dey cases is inappropriate. The DOJ’s memorandum in support of consolidation makes plain its intent to conflate separate cases involving different companies, different drugs, different periods, and different marketing and sales practices. Although the DOJ broadly refers to “parallel allegations,” “overlapping” proof, and its so-called “combined impact” theory, *nowhere* in its complaints against Roxane or Dey, in any of its summary judgment filings, or in its consolidation memorandum, does the DOJ allege any coordinated action between the Roxane and Dey Defendants. To the contrary, the Dey and Roxane cases have always been the subject of separate complaints wholly lacking in any allegations of *any* connection or conspiracy between Roxane and Dey. Indeed, a cursory inspection of the factual record, as well as the allegations in the DOJ’s complaints, reveals a wide divergence of allegations and evidence regarding the sales and marketing practices of these two distinct companies.

¹ BIPI and BIC have moved separately for summary judgment on the DOJ’s alter ego and direct liability claims because there is no evidence to establish the disfavored remedy of piercing BIC’s and BIPI’s corporate veils or to hold these separate companies directly liable for Roxane’s purported conduct. (*See* Dkt. Nos. 6191 & 6192) Because of similar risks of evidentiary confusion and prejudice, the Roxane Defendants reserve the right to file a motion to sever or for separate trials based on the DOJ’s joinder of Roxane, BIC, and BIPI in a single lawsuit.

The real purpose of the consolidation request is to ameliorate the chance that Roxane or Dey will be absolved for any portion of the DOJ's unprincipled damages request — even though the DOJ tacitly concedes that Roxane and Dey would not be held liable in separate trials for large portions of those alleged damages. (See Dkt. No. 6585, DOJ Mem. in Supp. of Consol. (“DOJ Mem.”) 14; Tr. of SJ Hr’g (Oct. 20, 2009) at 24-25 (attached as Ex. A)) In a consolidated trial, the DOJ leaves no doubt that it will seek to maximize its chance of recovery by holding each Defendant liable for any damages caused by the other’s independent conduct, even if that Defendant’s individual impact was “negligible.” But the DOJ’s “combined impact” theory has no cognizable basis under the False Claims Act (“FCA”), a quasi-criminal, punitive statute, and is simply intended to confuse the jury into awarding excessive damages.²

Moreover, even if the DOJ could establish its *prima facie* duty of showing significant judicial economy because of the overlap of some evidence, the DOJ’s consolidation proposal should be refused because of the high risk (if not certainty) of juror confusion and demonstrable prejudice to Defendants. In the nearly ten years since Ven-A-Care first filed the Roxane case, the DOJ has never taken a single step toward consolidation until now. The DOJ never amended either complaint to plead any coordinated or joint conduct between the Dey and Roxane Defendants and instead alleged stand-alone, individualized allegations of fraudulent conduct in each complaint. Having done so, the DOJ should not now be allowed to present to a single jury a misleading and prejudicial mixture of allegations, witnesses, and documents. This would create an exceptionally complex trial that would overwhelm and confuse any jury, burden the Court, and unfairly prejudice each Defendant’s right to show independently that it did nothing wrong.

² Because there are numerous arguments counseling against a consolidated trial of the Roxane and Dey Defendants, the Roxane Defendants do not intend to address in this opposition all of the legal deficiencies of the DOJ’s combined impact theory of liability. Suffice it to say, the Roxane Defendants disagree with the DOJ’s untenable theory and reserve their right to challenge its fallacies at a later date.

This Court has repeatedly noted the importance (and potential confusion) in separating Defendant- *and* drug-specific conduct — and with good reason. As other courts have observed:

The benefits of efficiency can never be purchased at the cost of fairness The systemic urge to aggregate litigation must not be allowed to trump our dedication to individual justice, and we must take care that each individual plaintiff's — and defendant's — cause not be lost in the shadow of a towering mass litigation.

Malcolm v. Nat'l Gypsum Co., 995 F. 2d 346, 350 (2d Cir. 1993). Here, the dangers of elevating a purported “efficiency” at the expense of a fundamental fairness are all the more palpable because the DOJ is seeking potentially catastrophic damages from Roxane in excess of \$1 billion. The stakes are enormous in this case, and Roxane is entitled to a trial that protects its ability to defend itself fairly and present its defenses to a jury unclouded by another Defendant's alleged good or bad acts. In short, Roxane should not have to explain to a jury why it did or did not do something that Dey did.

In addition to the grave prejudice a consolidated trial would impose on the Roxane Defendants, the DOJ's consolidation argument fails because the DOJ's purported “common issues of law and fact” are by and large not at all common. While some facts may be common, proof about whether any Defendant engaged in the individual conduct alleged in these separate cases would neither prove nor disprove the DOJ's allegations against any other Defendant. Thus, the DOJ's professed concern over potential “inconsistent adjudications” rings hollow. The Roxane and Dey cases are premised on different evidence, require individualized proof to support each element of each claim against each Defendant, and may not be of identical merit. Indeed, the notion that Dey should not be absolved of liability at trial simply because a jury could find Roxane liable, and *vice versa*, is absurd.

Because of the complex, individualized evidentiary presentation against each Defendant that the DOJ must make, a single trial will not significantly lessen the burden on the parties or the Court.

In short, the DOJ has not shown how the benefits of consolidation outweigh its costs, or how consolidation would promote judicial economy, given the serious challenges involved in a trial of distinct companies and different drugs. The Court should deny the DOJ's request for consolidation.

BACKGROUND

The DOJ's Claims Against The Roxane And Dey Defendants Are Based On Different Drugs, Different NDCs, And Different Time Periods.

To avoid repetition and duplication, the Roxane Defendants adopt and incorporate by reference Dey's description of the differences in these cases, set forth at pages 1-6 of Dey's opposition memorandum, and note the following additional differences. In its memorandum, the DOJ portrays these separate cases brought against two competing drug manufacturers as involving only one drug: ipratropium bromide. (DOJ Mem. 3) There are, however, eight other drug products at issue in the DOJ's case against Roxane that plainly have no connection to Dey. (Rox. First Am. Compl. ¶ 58; Dey Compl. ¶ 29 [Case No. 1:05-cv-11084-PBS, Dkt. No. # 184]) Moreover, the DOJ has sued Roxane for prices associated with thirty-five NDCs, and the DOJ has sued Dey for prices associated with twenty-six of its NDCs. (DOJ Mem. 3) The relevant period of the DOJ's claims also differs for the Roxane and Dey complaints. The DOJ's claims against Roxane, except for the claims related to ipratropium bromide, commence in 1999. (*Id.*) In contrast, the DOJ has sued Dey for claims dating back to 1992. (Dey Compl. ¶ 50) Even for ipratropium bromide, the DOJ has sued Roxane for the period beginning in June 1996, but has sued Dey only for the period beginning in January 1997. (DOJ Mem. 3) The evidentiary record for these cases thus covers significantly different periods and drug products.

These differences are compounded by the fact that while Roxane and Dey both manufacture generic drugs, the DOJ also alleges claims against Roxane based on its distinct marketing of a line of generic drugs known as "branded generics." (Dkt. No. 6293, DOJ Rox. SOF ¶¶ 7, 89-104) The

DOJ's claims with respect to the branded generics have unique issues, as a result of the different markets in which these drugs compete. (Dkt. No. 6425, Rox. Reply SOF ¶¶ 253-54; *see also* Rox. Resp. to DOJ SOF ¶ 91 (explaining that Oramorph SR was marketed based on its efficacy directly to physicians, who were not reimbursed by Medicare or Medicaid)) The DOJ does not allege that Dey marketed or sold any "branded generics" or marketed any of its drugs at issue based on efficacy, as opposed to price.

Dey and Roxane Had Different Practices With Respect To AWP And WAC.

Roxane and Dey also employed different practices with respect to the manner in which WAC and AWP were used during the relevant period. For example, while Roxane stopped providing WAC to drug pricing compendia in late 1997 and early 1998 for its generic products (Roxane SOF ¶¶ 113-14), Dey provided WAC throughout the relevant period. (Dkt. No. 6194, Dey SJ Br. 16) Moreover, by 1999, Dey sent price notification letters directly to state Medicaid administrators and to the DMERCs explaining that Dey's AWP was not the price actually charged or paid in the marketplace and that Dey's WAC was its undiscounted list price to wholesalers. (*Id.* at 22) Roxane did not send any comparable letter. Roxane also provided both AWP and WAC for its branded generic products until they were divested in 2001.³ (Roxane SOF ¶¶ 113-14)

The DOJ Predicates Its Claims Against The Roxane And Dey Defendants On Different Allegations And Evidence.

The DOJ has likewise alleged different theories of wrongful conduct with respect to the Dey and Roxane Defendants.⁴ The DOJ alleges Dey knowingly marketed the spread on its products

³ Notwithstanding this divestiture and the fact that Roxane no longer marketed or sold the divested products after September 2001, the DOJ claims that it seeks "Medicaid damages *for all drugs* through the first quarter of 2008 . . ." (*See* DOJ Mem. 3) There is, however, no basis for the DOJ's claims once these drugs were divested. In fact, the DOJ's expert expressly excluded these products from his calculation once they were divested in September 2001. (Rebuttal Report of M. Duggan, at 19-20 (attached as Ex. B))

⁴ The DOJ alludes to the fact that one of Roxane's many former employees, Mark Pope, previously worked for Dey. This fact has no relevance to the issue of consolidation, as there is no evidence that any of Mr. Pope's actions as a
(Continued...)

specifically for the purpose of providing an incentive to providers by “increasing the spread on Medicare/Medicaid reimbursements.” (Dey Compl. ¶ 53; Dkt. No. 6303, DOJ Dey SJ Br. 6-7; Dkt. No. 6296, DOJ Dey SOF ¶¶ 81, 93, 95-98) The DOJ has also attempted to gather evidence that Dey allegedly “collected and created an extensive database of information about state Medicaid reimbursement methodologies and Medicare reimbursement information.” (DOJ Dey SOF ¶ 89) The DOJ makes no similar allegation or reference to documentary evidence of Roxane’s alleged “marketing the spread.” Moreover, the DOJ’s allegations against the Roxane and Dey Defendants differ insofar as the DOJ has alleged alter-ego theories against Roxane’s corporate sibling, BIPI, and Roxane’s parent company, BIC. (*See* Rox. First Am. Compl. ¶¶ 19-20) The DOJ’s complaint against Dey does not contain any comparable theories.

ARGUMENT

I. LEGAL STANDARD OF RULE 42(A).

The threshold issue for consolidation in the First Circuit is whether the two proceedings involve common issues of fact or law. *Seguro De Servicio De Salud De Puerto Rico v. McAuto Systems Group, Inc.*, 878 F.2d 5, 8 (1st Cir. 1989); Fed. R. Civ. P. 42(a). However, “the mere existence of common issues, a prerequisite to consolidation, does not require consolidation.” *United States v. Dentsply Int’l, Inc.*, 190 F.R.D. 140, 143 (D. Del. 1999). In determining whether to consolidate, a court must weigh “the interest of judicial convenience against the potential for delay, confusion and prejudice caused by consolidation.” *Sw. Marine, Inc. v. Triple A Mach. Shop, Inc.*, 720 F. Supp. 805, 807 (N.D. Cal. 1989).⁵ Thus, consolidation may not be appropriate, even in light

Dey employee involved or otherwise implicated Roxane. In other words, Mr. Pope’s employment history is not in fact a “common fact” upon which to predicate consolidation, but rather another indication that the DOJ intends to bootstrap one Defendant against the other in a consolidated trial.

⁵ *See also Data Gen. Corp. v. Grumman Sys. Support Corp.*, 834 F. Supp. 477, 487 (D. Mass. 1992); *Arnold v. Eastern Air Lines, Inc.*, 712 F.2d 899, 906 (4th Cir. 1983) (“[A] trial must remain fair to both parties, and such

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of common issues, where the opposing party establishes that consolidation will cause “demonstrable prejudice” to it. *Gilliam v. Fidelity Management & Research Co.*, 2005 WL 1288105, at *1 (D. Mass. May 3, 2005). In such circumstances, the DOJ, as the party seeking consolidation, bears the burden of establishing that the benefits of consolidation trump the risk of any detriment that may result. *See Servants of the Paraclete, Inc. v. Great Am. Ins. Co.*, 866 F. Supp. 1560, 1572 (D.N.M. 1994); *In re Desmond*, 2005 WL 3116551, at *1 (Bankr. D.N.H. Sept. 20, 2005).

The DOJ argues that there is no demonstrable prejudice, and that jury instructions could somehow ameliorate that potential risk. (*See* DOJ Mem. 18) But this Court, as well as another state court handling similar AWP litigations, concluded that consolidation is not appropriate for these types of cases, and attempts to consolidate them for trial have resulted in significant problems. Dey’s opposition memorandum sets forth the concerns about juror confusion and prejudice that this Court and others have voiced on the prospect of consolidating AWP cases for trial. (*See* Dey Defs.’ Opp’n to Mot. to Consolidate Cases, Section I.A) There is no need to repeat those passages here, and each is expressly incorporated and adopted herein. Suffice it to say, this Court has recognized repeatedly that the significant differences from one company to the next require each company and its conduct to be considered independently at trial.

II. REGARDLESS OF ANY COMMONALITIES, THE UNACCEPTABLE RISKS OF JURY CONFUSION AND PREJUDICE GREATLY OUTWEIGH ANY EFFICIENCY THAT WOULD SUPPOSEDLY RESULT FROM CONSOLIDATION.

A. Consolidation Will Unduly Prejudice The Roxane Defendants And Deny Them Their Right To A Fair And Impartial Trial.

Because any evidence concerning Dey’s marketing, sales, or pricing conduct is not relevant

considerations of convenience may not prevail where the inevitable consequence to another party is harmful and serious prejudice.”); *Baker v. Waterman S.S. Corp.*, 11 F.R.D. 440, 441 (S.D.N.Y. 1951); 8 Moore’s Fed. Prac. § 42.10[4][a] (2009) (“In weighing the interests of convenience and economy against an ultimate goal of fairness and impartiality at trial, as well as individual justice, courts have found fairness must be paramount.”).

to the DOJ's claims against the Roxane Defendants, "consolidation would create a likelihood of prejudice by confusing the issues." *See Liberty Lincoln Mercury, Inc. v. Ford Mkt'g Corp.*, 149 F.R.D. 65, 81 (D.N.J. 1993) (denying consolidation because "in each case liability must be determined on a Dealer-by-Dealer, part-by-part, sale-by-sale basis, with consideration of facts that are highly specific to individual dealers. It simply is not enough that the two actions allege the same theory of recovery."). Melding together the factual and legal inquiries of separate cases in the name of efficiency will undermine, if not eliminate, each Defendant's ability to have a fair trial on the facts and evidence applicable to that Defendant.

The practical problem with consolidation here is that Dey-specific evidence is likely to be extremely prejudicial and irrelevant to the issue of Roxane's liability. In analogous circumstances, a federal district court recognized the prejudice likely to result from the court being "forced to admit evidence it would otherwise exclude and instruct the jury that the evidence can be considered only in support of the particular Plaintiff's claim, and cannot be considered in the claims of the other Plaintiffs." *Henderson v. AT&T Corp.*, 918 F. Supp. 1059, 1063 (S.D. Tex. 1996), *abrogated on other grounds by Holmes v. Energy Catering Servs., LLC*, 270 F. Supp. 2d 882, 886 (S.D. Tex. 2003).⁶ The DOJ will likely seek to admit irrelevant and prejudicial Dey evidence before the jury judging Roxane's conduct. Given the broad range of drugs and business practices at issue in the DOJ's separate cases and the different timeframes applicable to the DOJ's claims, a consolidated trial would invite the jury to make inappropriate comparisons between Dey and Roxane and, whether consciously or subconsciously, to attribute or compare one Defendant's conduct to another's. The inevitable evidence mottling will unfairly prejudice the Roxane and Dey

⁶ The *Henderson* court specifically disavowed the efficacy of limiting instructions to curtail juror confusion, noting that because "a joint trial would make it extremely difficult for the jury to keep each Plaintiff's claim separate and require each Plaintiff to independently prove her case, the jury may simply resolve the confusion by considering all the testimony to pertain to all the claims, despite any limiting instructions." *Id.* at 1063-64.

Defendants because each Defendant will be forced to explain its conduct in light of evidence attributable solely to the other Defendant.

For example, as noted above, Dey provided WACs for its products to the compendia throughout the relevant period in its case. Dey also sent price notification letters directly to state Medicaid administrators and to the DMERCs explaining the significance of its AWP and WACs. Comparing this information with the information communicated by Roxane could lead the jury to conclude — based on the fact that Roxane did not provide WAC for most of its drugs or the pricing letters explaining the significance of its AWP and WAC — that Roxane purposefully misrepresented its pricing information. It was exactly this kind of proposed combination of different companies and different models that led another court to deny consolidation in an AWP case. That court concluded: “I don’t want the industry to be painted with one broad brush[.]” (Tr. of Mot. Hr’g, *Wisconsin v. Abbott Labs., et al.* (Mar. 10, 2009) at 13-14 (attached as Ex. C)) In these circumstances, separate cases are required to ensure that no Defendant is prejudiced by the presentation of evidence that would be inadmissible as to it specifically. *See* 9A Wright & Miller, Fed. Prac. § 2388 (2009) (separate trial may be ordered to avoid prejudice, “as when evidence admissible only on a certain issue may prejudice a party in the minds of the jury on other issues”).

Moreover, Roxane will likely present factual and legal arguments that may appear inconsistent with, or even inimical to, defense theories offered by Dey.⁷ The Roxane Defendants are entitled to an individualized determination on the merits of their own defenses, apart from the disparate facts, conduct, and circumstances pertaining to Dey. As this Court has noted: “[T]here

⁷ For example, a consolidated trial will unduly prejudice Roxane with respect to the issue of the DOJ’s inclusion of the Novaplus products into the Medicare arrays. In a consolidated trial, the DOJ’s theory of Medicare damages, premised on the inclusion of Novaplus products erroneously being classified as brands, all but forces Dey to agree with the DOJ’s arguments regardless of actual merit — and there is none — because it would eliminate Dey’s liability for Medicare damages.

are different issues, and you all have the right to present it your own way. . . .” (Tr. of Settlement Status Conference (May 22, 2007) at 30 (attached as Ex. D)). A single trial involving Roxane and Dey – and the approximately eleven different drug products, covering both generic and branded generic drugs, and sixty-one NDCs in total — would interfere with this right, and would be prejudicial to both Defendants.

B. The Sheer Complexity Of Defendant-Specific Evidence Will Confuse A Single Jury.

The complexities of these cases will be magnified when it comes time for the jury to apply the relevant law to each Defendant’s own unique set of facts. *See In re Desmond*, 2005 WL 3116551, at *1 (finding that “although the consolidation may be convenient for the Movants, it may create confusion by combining already complicated claims”). Evaluating the evidence associated with Roxane’s thirty-five NDCs and nine different drug products will be cumbersome enough for jurors — asking them to evaluate Dey’s separate and distinct conduct, across a different timeframe, for its twenty-six NDCs and three separate drug products, will be next to impossible. *See Gilliam*, 2005 WL 1288105, at *3 (“The likely confusion at trial regarding what evidence applies to which case as well as the calculations of damages spanning different time periods counsels against consolidation.”).

A consolidated trial against the Roxane and Dey Defendants would require a single jury to evaluate evidence specific to each Defendant, including documentary evidence and the testimony of both fact and expert witnesses, for each of the twelve drugs at issue for each element of the DOJ’s three claims for over a fifteen-year period. And to consolidate here would give the DOJ “a chance to do something not many other civil litigants can do — overwhelm a jury with evidence.” *Cain v. Armstrong World Indus.*, 785 F. Supp. 1448, 1457 (S.D. Ala. 1992). As courts have recognized and is true here, “[c]onsolidation is improper when the introduction of ‘voluminous’ evidence, relevant

to one of the consolidated actions but irrelevant to another, impairs the conduct of trial.” *Hasman v. G.D. Searle & Co.*, 106 F.R.D. 459, 461 (E.D. Mich. 1985).⁸

The Roxane and Dey Defendants are entitled to have the evidence concerning the pricing, marketing and sales of their individual products judged on the merits without comparisons to how that evidence stacks up against the conduct of others.⁹ But, in a consolidated trial, a single jury would be forced to confront so much information about similar, but distinct, matters that it will be impossible for the jury to parse through and draw necessary distinctions between evidence applicable to each Defendant. Nor is it likely that they would be able to grasp the evidentiary nuances between the Roxane and Dey Defendants. Indeed, rather than separately analyzing the evidence pertinent to each Defendant and each drug, the jury would consider the whole mass of evidence as relevant to all Defendants. No jury instruction, however detailed, could assist the jurors in successfully sorting and sifting through “the cosmic sweep of the factual data” that the jury would have to absorb here. *See Malcolm*, 995 F. 2d at 353 (even where trial court took precautions “to assure that each case maintained its identity, . . . the shear breadth of the evidence made these precautions feckless in preventing jury confusion” and ultimately “the jury thr[ew] up its hands in the face of a torrent of evidence”).

* * *

Accordingly, the Court should exercise its discretion to deny consolidation because the

⁸ *See also Liqui-Box Corp. v. Reid Valve Co.*, 1989 U.S. Dist. LEXIS 17189, at *3 (W.D. Pa. Sept. 15, 1989) (“Where the evidence in one case is not relevant to the issues in the other, consolidation would create a likelihood of prejudice by confusing the issues.”); *Dixon v. CSX Transp. Inc.*, 990 F.2d 1440, 1444-45 (4th Cir. 1993) (vacating consolidation of claims where evidence introduced as relevant to one claim was irrelevant and inflammatory as to another).

⁹ *See Webb v. Goord*, 197 F.R.D. 98, 101 (S.D.N.Y. 2000) (“Combining into a single action unrelated incidents involving distinct events and disparate parties also carries the potential of confusing a jury and of exposing some defendants to the risk of liability by loose institutional association for the unconnected wrongdoing of others.”); 8 Moore’s Fed. Prac. § 42.13[1] (2009) (“An order of consolidation for trial, as opposed to one solely for consolidated pretrial proceedings, may have the effect of denying a party his due process right to prosecute his own separate and distinct claims or defenses without having them so merged into the claims or defenses of others that irreparable injury will result.”).

danger of prejudice and confusion outweighs any potential efficiency cited by the DOJ. *See Phelps v. Bd. of Educ. of Topeka Unified Sch. Dist. #501*, 1986 U.S. Dist. LEXIS 25518, at *3 (D. Kan. May 14, 1986); *Lewis v. Four B Corp.*, 347 F. Supp. 2d 1017, 1020 (D. Kan. 2004).

III. THE DOJ'S NOVEL THEORY OF "COMMON" CAUSATION AND DAMAGES DOES NOT EXIST UNDER THE FCA AND CANNOT SERVE AS A PREDICATE FOR CONSOLIDATION.

The DOJ seeks to consolidate the Roxane and Dey Defendants for trial based on its novel and entirely unsupported "combined impact" theory. The DOJ argues (with no supporting legal citation) "that Dey and Roxane are each legal causes of the combined impact their price reporting had on Medicare spending for Ipratropium Bromide" and that "proving damages in either case will of necessity require evidence of both companies' price reporting and both companies' impact on the Medicare program." (DOJ Mem. 14, 16) The DOJ's argument is not only legally wrong in light of the law of this Court, which requires a defendant's liability and damages to be evaluated based on its own individual conduct, on a drug-by-drug basis, *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 144, 155 (D. Mass. 2008); *In re Pharm. Indus. AWP Litig.*, 491 F. Supp. 2d 20, 99 (D. Mass. 2007), but also reveals the danger of the DOJ's consolidation request, which "will of necessity" unfairly force Roxane to defend against the evidence specific to Dey's conduct.

This Court has previously determined that general causation principles derived from tort law are applicable to the FCA. *United States ex rel. Franklin v. Parke-Davis*, 2003 WL 22048255 at *4-*6 (D. Mass. Aug. 22, 2003). One of these general principles, proximate causation, requires that in order for a defendant to be held liable for its conduct, the resulting damage must be foreseeable and have a sufficiently close causal connection to the defendant's purported conduct. *Id.* at *4-*5. Because the FCA is a "quasi-criminal," punitive statute, courts typically apply a proximate causation standard to "narrow, rather than enlarge, the field of actions for which FCA liability may be imposed." *United States ex rel. Sikkenga v. Regence Bluecross Blueshield*, 472 F.3d 702,

714-15 & n.17 (10th Cir. 2006). In fact, this Court has limited causation under the FCA, requiring that a defendant must actively participate in the process of submitting the allegedly false claims at issue in order to be held liable. *See United States v. President & Fellows of Harvard College*, 323 F. Supp. 2d 151, 186 (D. Mass. 2004). And when the misconduct of a third party causes damages that would not have resulted from the defendant's actions alone, the third party's actions are an intervening cause that cuts off the defendant's liability. *Russo v. Baxter Healthcare Corp.*, 140 F.3d 6, 11 (1st Cir. 1998).¹⁰

Here, the DOJ does not allege or provide a shred of evidence that Roxane "actively participated" in Dey's pricing and marketing decisions. Nor is there any evidence that Roxane otherwise proximately caused the damages that purportedly flowed from Dey's conduct. In fact, the record evidence makes clear that Roxane and Dey were fierce competitors in the marketplace, did not control or participate in the pricing decisions of one another, and acted independently of each other and pursuant to their own business interests. (*See* Dkt. 6296 at ¶ 145) As a result, there is no evidence that Roxane could have foreseen the basis for the DOJ's claims against Dey with respect to the marketing and sale of its drugs. Dey's alleged wrongful conduct is the quintessential intervening cause that cuts off Roxane's liability for any damages attributable to Dey. *See Russo*, 140 F.3d at 11 (attorney's legal malpractice cut off defendant's liability); *see also* Restatement (Second) of Torts § 442. Thus, the DOJ's novel and unsupported "combined impact" theory fails as a matter of law and cannot serve as a basis for consolidation. (*See* DOJ Mem. 14) In short, the Roxane Defendants cannot be the legal cause of any injury they have not individually caused. *In re*

¹⁰ *See also United States ex rel. Fago v. M & T Mortg. Corp.*, 518 F. Supp. 2d 108, 122 (D.D.C. 2007) (granting defendant summary judgment under FCA because mortgage borrower defaults were intervening cause that cut off defendant's liability for forged signatures on loan applications); *United States ex rel. Kinney v. Hennepin County Med. Ctr.*, 2001 WL 964011, at *10 (D. Minn. Aug. 22, 2001) (dismissing FCA claim for lack of causation where an automated billing system, not defendant's initial certifications, resulted in filing claims under an improper Medicare billing code).

Pharm. Indus. AWP Litig., 491 F. Supp. 2d at 99.

IV. CRITICAL ISSUES ARE NOT COMMON AND SHOULD NOT BE PRESENTED AS SUCH TO A JURY.

Although the DOJ contends that a “trial will be based in no small measure on a common factual record,” the DOJ’s claims against the Roxane and Dey Defendants admittedly do not arise from the same transaction or occurrence. (*See* DOJ Mem. 1-4) Instead, each case implicates a wide variety of differences — different legal theories and different evidence, consisting of different conduct, involving different drug products, different NDCs, different timeframes, and different persons. The only overarching common “issue” in these cases is that they implicate Medicaid and Medicare reimbursement and one common drug (among the eleven others at issue). (*See id* at 4-5, 13) That is insufficient to demonstrate commonality.¹¹ *See Liberty Lincoln*, 149 F.R.D. at 81 (finding “the mere fact that two cases assert similar theories of recovery does not constitute a ‘common question of law’ so as to warrant consolidation”); *Grayson v. K-Mart Corp.*, 849 F. Supp. 785, 789 (N.D. Ga. 1994) (finding “a complete lack of common questions of fact or law” in the severance context where “the factual and legal questions between the plaintiffs and the defendant are based upon the wholly separate acts of the defendant with respect to each plaintiff”).¹²

¹¹ Although Roxane and Dey have largely coordinated discovery at this Court’s urging and behest (*see* DOJ Mem. 9-11), they have not coordinated defensive discovery. Moreover, the fact that there was coordinated discovery does not warrant consolidation for trial. It is well-recognized that “[a]n order of consolidation for trial, as opposed to one solely for consolidated pre-trial proceedings, may have the effect of ‘deny[ing] a party his due process right to prosecute his own separate and distinct claims or defenses without having them so merged into the claims or defenses of others that irreparably injury will result.’” 8 Moore’s Federal Practice § 42.13[1], at 42-28 (3d ed. 2007). *See also Blasko v. Washington Metro. Area Transit Auth.*, 243 F.R.D. 13 (D.D.C. 2007) That is the outcome the DOJ’s request for consolidation will bring about here.

¹² The cases the DOJ cites are inapposite and do not alter the conclusion that consolidating the Roxane and Dey cases is inappropriate. *See Cruickshank v. Clean Seas Co.*, 402 F. Supp. 2d 328, 340 (D. Mass. 2005) (consolidating two cases involving damages from the same defective boat paint); *Storlazzi v. Bakey*, 1995 WL 623676, at *1 (1st Cir. Oct. 24, 1995) (affirming consolidation of former teacher’s three cases against different combinations of the same defendants for the same wrongful termination claim); *Hendrix v. Raybestos-Manhattan, Inc.*, 776 F.2d 1492, 1496 (11th Cir. 1985) (consolidating four out of 44 asbestos cases because the plaintiffs each worked at the same workplace, each was exposed to asbestos in the same timeframe, and the alleged asbestos-related disease had similarly progressed in each victim). Indeed, in the *Gilliam v. Fidelity Management & Research Co.* decision cited

(Continued...)

The DOJ's claims are based on independent and unrelated transactions involving pricing decisions made by different companies according to their own particularized business models and their own drug products. The Roxane and Dey complaints make plain that these cases do not involve claims arising out of the same transaction or series of transactions. (Rox. First Am. Compl. ¶ 2; Dey Compl. ¶ 2) And neither complaint alleges conspiracy or concerted action between or among the Roxane Defendants and Dey, instead alleging that each independently and "fraudulently" caused injury. (See Rox. First Am. Compl. ¶ 2; Dey Compl. ¶ 2) Because these facts and allegations of these cases would render a joint proceeding impractical, consolidation should be rejected. See *Fleishman v. Prudential-Bache Secs., Inc.*, 103 F.R.D. 623, 625 (E.D. Wis. 1984) ("[w]hile there is clearly a commonality of legal issues, and while the cases may share certain issues of material fact, factual dissimilarities in these cases render consolidation impractical from an administrative standpoint"). Indeed, consolidation is particularly suspect in this case, where marketing and sales practices are at issue, because the evidence used by the DOJ against one Defendant cannot apply in both cases without unduly prejudicing the other Defendant, as discussed above. See *In re Consol. Parlodel Litig.*, 182 F.R.D. 441, 446 (D.N.J. 1998); *Liberty Lincoln*, 149 F.R.D. at 81. In any event, as highlighted below, none of the critical issues is common.

A. The FCA Requires Individualized Proof of Falsity And Intent.

The DOJ argues erroneously that these cases involve a common question of whether "defendants' reported AWP's were false." (DOJ Mem. 12) This Court has repeatedly made clear, however, that plaintiffs must prove the falsity of AWP on a company-by-company, drug-by-drug basis. See, e.g., *In re Pharm. Indus. AWP Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003). Thus, the DOJ's allegedly "common" question is not common at all — it requires *individualized* proof at

by DOJ, the court declined to consolidate two matters because of the "likely confusion at trial regarding what evidence applies to which case." 2005 WL 1288105, at *3 (D. Mass. May 3, 2005).

trial. Moreover, Roxane and Dey's practices regarding AWP and WAC differed significantly, and changed materially and in different ways over the time period at issue. (*See supra* at 5) As a result, there is no evidence common to the Roxane and Dey Defendants from which the DOJ can attempt to prove that Defendants' individual representations were universally false.

In addition, the DOJ must show that each Defendant possessed the requisite scienter. *See Allison Engine Co., v. United States ex rel. Sanders*, 128 S. Ct. 2123, 2130 (2008); *Harvard College*, 323 F. Supp. 2d at 188; *United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 46 (D. Mass. 2009).¹³ In asserting its separate claims against the Roxane and Dey Defendants, the DOJ argues that its proof of FCA violations presents a common issue because each Defendant is alleged to have "report[ed] false prices to third-party pricing compendia with the *intended* purpose of increasing Medicare and Medicaid reimbursement to healthcare providers who purchased the defendants' products." (*See* DOJ Mem. 2 (emphasis added)) But the DOJ premises all of its claims on allegations that *each* Defendant acted "knowingly" and "purposefully." (*See, e.g.,* Rox. First Am. Compl. ¶¶ 2-8, 58-68, 70, 73, 75, 77; Dey Compl. ¶¶ 2-6, 50-61, 63, 66, 68, 70) Thus, by definition, each Defendant's alleged knowledge and intent is a highly individualized inquiry, involving Defendant-specific evidence for each of the sixty-one NDCs at issue. Proof of what Roxane "knew" or "intended" has no bearing on what Dey "knew" or "intended" for purposes of assessing liability on a given NDC.

B. The FCA Requires Individualized Proof of Causation and Damages.

Likewise, causation under the FCA requires defendant-specific evidence. *See Harvard College*, 323 F. Supp. 2d at 186, 189. And evidence of damages, if any, must be presented and

¹³ A similarly individualized inquiry will be required to evaluate the DOJ's unjust enrichment claims, which are predicated on the same allegations of purportedly willful and fraudulent conduct of each individual Defendant. (*See* Dey Compl. ¶¶ 68-71; Rox. First Am. Compl. ¶¶ 75-78)

evaluated on an individual NDC-by-NDC basis. Thus, given the large number of different drug products at issue, a joint trial of these two cases will require extensive testimony and proof with respect to each of Defendant's drugs. In fact, the DOJ itself has acknowledged that any calculation of its supposed "overpayments" will require manufacturer-specific and drug-specific data of each Defendant. There is nothing "common" about these critical inquiries.

V. CONSOLIDATION WILL NOT PROMOTE JUDICIAL ECONOMY AND ANY RISK OF INCONSISTENT JUDGMENT IS INCONSEQUENTIAL.

In light of the numerous and wide-ranging evidentiary differences among the cases the DOJ seeks to consolidate, the judicial time-saving that the DOJ argues is a false economy. (*See* DOJ Mem. 13) First, a consolidated trial would last considerably longer than a trial against an individual company, and would require significant additional work on motion practice, evidentiary evaluation, jury instructions, and verdict forms to assist in jurors' attempts to separate the various Defendants and claims. Second, consolidation would not relieve the DOJ from its obligation to introduce evidence regarding the specific conduct and intentions of each Defendant and each of the separate drugs at issue.

Moreover, the purported "risk" of "inconsistent adjudication" is virtually nonexistent.¹⁴ The DOJ brought separate lawsuits against different companies selling and marketing different drugs in different ways. The DOJ's disparate claims may not all be of identical merit. Thus, as a result of the differences in evidence and legal theories against each Defendant, as well as burdens of production and persuasion with respect to each company, there is no risk of inconsistent judgments

¹⁴ DOJ's reliance on *Int'l Paving Systems, Inc. v. Van-Tulco, Inc.*, is misplaced. (DOJ Mem. 16-17, citing *Int'l Paving*, 806 F. Supp. 17, 22 (E.D.N.Y. 1992)) In that decision, the court allowed consolidation of two separate actions — an action against a general contractor for breach of contract based on defective construction and an action involving the same general contractor's counterclaim against its sub-contractor for a determination that the sub-contractor was responsible for that alleged construction defect. *Id.* Thus, *International Paving*, unlike this case, depended on the same evidence regarding the same alleged defect.

in trying these cases separately.

VI. AT A MINIMUM, THE COURT SHOULD EMPANEL SEPARATE ROXANE AND DEY JURIES TO HEAR DEFENDANT-SPECIFIC EVIDENCE AS A MEANS TO MINIMIZE PREJUDICE.

If the Court is at all inclined to consolidate these cases over Defendants' objections, it should invoke its discretionary authority under Fed. R. Civ. P. 42(a) to join for trial only common issues such as the reimbursement methodologies of the Medicare and Medicaid programs and "government knowledge" evidence concerning, *inter alia*, whether the Government or state Medicaid programs relied on AWP's to satisfy legitimate policy objectives, such as incentives to use cheaper generics, cross-subsidization for inadequate dispensing fees (recognizing that the issue of inhalation dispensing fees presents a separate question), and beneficiary access.¹⁵ See Fed. R. Civ. P. 42(a).

Under the alternative arrangement suggested here, a limited common presentation would not sacrifice fairness to Defendants. The common evidence could be presented jointly before Roxane and Dey juries. Those jurors, however, would not be allowed to hear any evidence relating to an individual Defendant other than the one for which they have been impaneled, which may mean that some portions of examinations or evidence could only be presented in front of a single jury. *Cf. United States v. Lebron-Gonzales*, 816 F.2d 823, 830-31 (1st Cir. 1987) (upholding trial court's decision to impanel two juries to decide cases as to different defendants, where both juries simultaneously heard government evidence common to all defendants, and only the jury deciding one defendant's case heard evidence pertaining solely to that case).¹⁶ While the logistics of such

¹⁵ As set forth in the Combined Memorandum Of Defendants In Opposition To The United States' Cross-Motions For Partial Summary Judgment, the DOJ's theory of "approval" (DOJ Mem. 2) is wrong as a matter of law. (Dkt. No. 6429, at 21-24)

¹⁶ *Smith v. DeRobertis*, 758 F.2d 1151 (7th Cir. 1985) (affirming district court's use of double-jury procedure and recognizing the balance it may strike between promoting judicial economy and reducing the prejudice to two
(Continued...)

arrangement might seem difficult, the prejudice outlined above makes a single unified trial untenable.

CONCLUSION

For all the foregoing reasons, the Court should deny the DOJ's Motion to Consolidate Cases For Trial.

Dated: November 2, 2009

Respectfully submitted,

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defendants that would occur in a joint trial); *Brown v. Simons*, 515 F.3d 1072, 1078 (10th Cir. 2008) (affirming use of dual-jury procedure whereby both juries heard common evidence simultaneously, and evidence admissible only as to one defendant was presented to that defendant's jury only).

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on November 2, 2009, a copy to LexisNexis File and Serve for posting and notification to all parties.

/s/ John W. Reale

John W. Reale